Serial No.	09/810,988
Applicant:	Gerhard Scheuch *et al.*
Filed:	March 16, 2001
Title:	DEVICE FOR THE CONTROLLED INHALATION OF THERAPEUTIC AEROSOLS
Art Unit:	3731
Examiner:	Clinton Ostrup
Confirmation Number:	7304
Attorney Docket No.:	RVOS-E1341US

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Alexandria, VA 22313-1450

DECLARATION UNDER 37 CFR § 1.132

In response to the Office Action dated September 30, 2009, I, Bernhard Muellinger, do hereby declare and say as follows:

BACKGROUND INFORMATION

1. I am a co-inventor of the present application.

2. I obtained a degree in Precision and Micromechanical Engineering in 1995 from the University of Applied Science in Munich, with a focus on medical device technology.

3. From 1995 to 1998, I was employed at the GSF – Research Centre for Environment and Health, working on the research project "Optimization of Aerosol Deposition with Monodisperse Encapsulated Particles". I held different positions related to aerosol research while I was at GSF.

4. From 1998 to 2000, I was employed at the Asklepios Clinics in cooperation with the Clinical Research Group of GSF and developed new pulmonary diagnostic technologies and performed clinical trials in aerosol delivery research.

5. Since 2000, I have been employed at Activaero GmbH. I am currently the Vice President of Device & Clinical Development, and I am responsible for medical device development and clinical development. I have managed numerous projects developing products including the AKITA® inhalation system, the AKITA²™ inhalation system, the AKITA JET™ inhalation system and several customer specific medical devices. I am also responsible for optimization of pharmaceutical formulations, dosing and aerosol targeting strategies in preclinical and clinical drug development projects within Activaero GmbH. I have extensive experience in clinical trials in drug delivery by aerosols.

THE APPLICATION

6. I have read and understood the above referenced patent application, including the specification, claims and the relevant prior art.

7. The standard I used for obviousness is whether the claims would have been obvious to an ordinary person skilled in the art in light of the references cited.

8. The Examiner rejected independent claims 25, 43, and 44 as being obvious over Brand (6,606,989) in view of Brooker (6,269,810) taken together with Goodman et al. (5,542,410).

9. As discussed in my Declaration dated July 17, 2008, Brand does not teach or suggest individually adjusting the inhalation device to the patient to be treated by adapting a dosage of at least one aerosol on the basis of the aerosol parameters to obtain a predetermined amount of aerosol deposition in a lung of the patient and Brand does not teach or suggest adjusting flow rate or tidal volume of an inhalation device based on inhalation parameters.

10. Regarding Brooker, in the last office action dated March 20, 2009, the Examiner stated "[s]ince the adjusted pulse would make up a portion of the respiratory flow or the tidal volume, and given that tidal volume is the lung volume representing the normal volume of air displaced between normal inhalation and exhalation when extra effort is not applied, the adjustment of the pulse would adjust the respiratory flow or tidal volume (at least to some extent)" (office action dated March 20, 2009, page 11, lines 12-16, see also page 8, lines 7-12).

11. Even accepting that the adjusted pulse would make up a portion of the tidal volume, it cannot be concluded that adjustment of the pulse would adjust the tidal volume to any extent. In Brooker, the adjusted pulse (volume) cannot adjust the tidal volume as the tidal volume in Brooker is determined by the way the patient breathes. If the patient does not breathe regularly but has an irregular breathing pattern, the tidal volume for each breath is different despite having an adjusted pulse volume. In addition, the adjusted pulse would not make up a portion of the respiratory flow as it is just a volume aerosol and not a "flow". Thus, I respectfully submit that the Examiner's statement above is incorrect.

12. Brooker does not teach or suggest individually adjusting the inhalation device to the patient to be treated by adapting a dosage of at least one aerosol on the basis of the aerosol parameters to obtain a predetermined amount of aerosol deposition in a lung of the patient. More specifically, Brooker does not teach or suggest adjusting flow rate or tidal volume of an inhalation device using individual patient parameters or aerosol parameters.

13. Therefore Brooker does not teach the elements in claims 25, 43, and 44 missing from Brand.

14. Goodman also does not teach or suggest adjusting flow rate or tidal volume of an inhalation device using individual patient parameters or aerosol parameters.

15. Tidal volume is the volume of air inhaled and exhaled with each breath. Tidal volume and respiratory flow both relate to air entering and leaving a patient's lungs during a breath.

16. Goodman teaches adjusting aerosol delivery based on inspiratory flow, pause, expiratory flow, and tidal volume. Adjusting aerosol delivery based on certain parameters is completely different than adjusting tidal volume.

17. Goodman teaches measuring, analyzing, and detecting respiratory flow and adjusting aerosol delivering based on measured respiratory flow. Measuring, analyzing and detecting respiratory flow is not the same as adjusting respiratory flow.

18. Goodman does teach trying to get the patient to adjust their breathing. However, this is also very different than adjusting a respiratory flow or tidal volume of an inhalation device.

19. Goodman does not teach or suggest adjusting respiratory flow or tidal volume of an inhalation device in any way. Consequently, Goodman can not teach or suggest adjusting respiratory flow or tidal volume of the inhalation device based on individual patient parameters or aerosol parameters.

20. Goodman is merely a variable dose inhaler. It still provides a metered dose; the amount of medication in that particular dose just varies from patient to patient.

21. Therefore, Goodman does not teach the elements in claims 25, 43, and 44 missing from Brand and Brooker.

22. I am not aware of any disclosure prior to the current invention that teaches or suggests adjusting the tidal volume or respiratory flow of an inhalation device, as claimed in claims 25, 43, and 44.

23. The present invention is an enormous step forward in inhalation devices and it is recognized by those skilled in the art as being at the forefront of technology.

24. The claimed invention permits much more efficient deposition of the drug in the lung than the prior art, which, in turn, results in a decrease of the amount of the necessary drug, which subsequently results in a substantial cost reduction.

25. In the prior art, it was impossible to adjust an inhalation device individually to the specific needs of a specific patient and to an individual drug. The inhalation device of the present invention overcomes these shortcomings, and individualizes the inhalation device to each patient.

26. The present invention was the first to introduce individualized inhalation. A much more optimized inhalation of an aerosol is obtainable if the respiratory flow and the tidal volume are individually selected for the specific patient. Thus, with the inventive inhalation device, controlled inhalation is provided with high accuracy: the drug indeed reaches the target area in the lung. To my knowledge, such a controlled and targeted inhalation has not been achieved in the art prior to the present invention.

CONCLUSION

Based on the above analysis, I conclude that the claims in the present patent application are not obvious over any combination of the references cited.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Dated: 11 November 2009 By: Bernhard Muellinger

Bernhard Muellinger